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Dennis O'Brien

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EXAMINER

YABUT, DIANE D

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/725,178
Filing Date: December 01, 2003
Appellant(s): O'BRIEN ET AL.

Jennifer L. Buss
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/11/2008 appealing from the Office action mailed 10/02/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

1. Claim 5 is currently rejected under 35 U.S.C. 102(b) as being anticipated by Barath, U.S. Patent No. 5,616,149.
2. Claim 9 is currently rejected under 35 U.S.C. 103(a) as being unpatentable over Barath, U.S. Patent No. 5,616,149 in view of Vigil et al., U.S. Patent No. 5,320,634.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,616,149	BARATH	04-1997
5,320,634	VIGIL ET AL.	06-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 2, 5, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Barath** (U.S. Patent No. **5,616,149**).

Claim 1: Barath discloses an elongated balloon **2** defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration, and an elongated incising element **6** mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue, and a radially compressible sheath **17** mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration (Figures 11-13; col. 5, lines 14-36).

Claim 2: Barath discloses a mounting pad **13** for attaching said incising element to said balloon (col. 5, lines 14-19).

Claim 5: Barath discloses a sheath having a pair of sheath members (on either side of incising elements **6**) being positioned on said balloon to interpose said incising element between said sheath members (Figures 12-13).

Claim 8: Barath discloses said incising element **6** being a blade and said surface feature is a cutting edge (col. 5, lines 14-36).

Claim 10: Barath discloses said cutting edge of said blade **6** being embedded in said sheath **17** when said balloon **2** is initially in said first configuration, said cutting edge oriented relative to said balloon to cut through said sheath for exposure of said cutting edge to incise tissue during radial compression of said sheath (Figures 11-13; col. 5, lines 14-36).

2. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**).

Claims 11-14: Barath discloses the claimed device except for the incising element being a round wire or made of a hardened polymer, and the sheath being made of a low durometer material or a porous polyurethane material. It would have been obvious to one of ordinary skill in the art at the time of invention to provide these materials to the incising element and sheath of Barath, since it was known in the art that these are beneficial as biocompatible materials that facilitate the cutting mechanisms in angioplasty procedures.

3. Claims 3-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** (U.S. Patent No. **5,616,149**) in view of **Vigil et al.** (U.S. Patent No. **5,320,634**).

Claims 3 and 9: Barath discloses the claimed device, including each sheath member having an azimuthal width w , and wherein said blade **6** has an azimuthal width, W ,

Art Unit: 3700

where said blade extends from said mounting pad, with $w > 2W$ (since the blade **6** is substantially thin compared to the widths of the sheath between the grooves **18**, as seen in Figures 12-13), but does not expressly disclose the incising element being partially encapsulated in said mounting pad and said mounting pad is bonded to said balloon.

Vigil et al. teach an incising element **31** being partially encapsulated in said mounting pad **32** and said mounting pad is bonded to said balloon **18** (Figure 3A; col. 4, lines 17-34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the incising elements as partially encapsulated in said mounting pad, as taught by Vigil et al., to Barath in order keep the incising element covered or protected and more securely mounted to prevent detachment from balloon.

Claim 4: Barath discloses the sheath **17** being attached to said mounting pad **13** (Figures 12-13).

(10) Response to Argument

1. Appellant argues that Barath does not teach or suggest that the sheath **17** is radially compressed to expose the surface feature, or cutting edge **6**, for tissue incision, as recited in the independent claim 1, but instead Barath teaches that inflation of the balloon **2** exposes the cutting edges **6**, not radial compression of the sheath, by increasing the size of the longitudinal grooves through which the cutting edges **6** are exposed. The examiner disagrees. Claim 1 of the present invention recites that the sheath is

"positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision" (lines 11-12). In Figures 12-13 of Barath, the sheath 17 is shown being positioned for radial compression between the tissue 7 and the balloon 2 while also exposing the surface feature 6. Radial compression of the sheath 17 may be achieved during inflation of the balloon, wherein the sheath may be pressed and held between the tissue and the balloon, while also exposing the surface features 6, and therefore the device of Barath reads on this limitation. It is also not recited in claim 1 to radially compress the sheath in order to cause the cutting edges to go from an unexposed position to an exposed position, and therefore the device of Barath reads on this limitation. In other words, the features upon which the appellant relies (i.e., radial compression of the sheath causing exposure of the cutting edge) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

2. The appellant also argues that Barath does not disclose the sheath 17 being attached to the mounting pad 13 since the sheath 17 is disposed about the balloon 2 with the sheath being a distance away from the surface of the balloon. However, the sheath covers the entire balloon and acts as a unit with the balloon during inflation and deflation, and therefore is considered to be attached, albeit indirectly, to the mounting pad 13 of

the balloon.

3. Appellant argues that claims 2-5 and 8-14 are patentable because they depend from claim 1. However, since Barath meets all the limitations of claim 1, the rejections of claims 2, 5, 8, 10 as being anticipated by Barath and the rejections of claims 11-14 as being obvious over Barath and the rejections of claims 3-4 and 9 as being obvious over Barath and Vigil et al. are also proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) Reopen prosecution. Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Diane Yabut/

Examiner, Art Unit 3734

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Frederick R Schmidt/

Director, Technology Center

Art Unit: 3700

Conferees:

Todd Manahan

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731

Marc Jimenez

/Marc Jimenez/

TQAS TC 3700